HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

D1149B

4298 Elysian Fields Avenue
New Orleans, LA 70122

January 31, 1997

WARNING LETTER NO.97-NOL-28

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Judy Kennedy Storer, President
Red Ball Medical Supply, Inc.
1020 North Market Street
Shreveport, Louisiana 71107

Dear Ms. Storer:

During an inspection of your facility, located at 1020 North Market Street, Shreveport, Louisiana, our investigator documented deviations from the Good Manufacturing Practices Regulations (Title 21 Code of Federal Regulations, Part 211) regarding your firm's medical liquid oxygen manufacturing operation. These deviations cause your product, oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection, during January 7,10,14, and 15, 1997, revealed the following objectionable conditions: failure to document and maintain complete records of the periodic calibration of your oxygen analyzer; failure to document and maintain complete records as proof of completing identity and strength assays on five lots of incoming liquid oxygen prior to filling and distributing the associated liquid home units; failure to document and maintain complete records as proof of completing identity and strength assays on liquid home units transfilled with the same five lots of incoming liquid oxygen; failure to establish batch production or control records, including pre-fill checks on cryogenic vessels, for each batch of liquid oxygen transfilled; and failure to establish written procedures designed to ensure that required tests are completed on every incoming lot of liquid oxygen.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Rebecca A. Asente, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3848, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Asente.

Sincerely,

James E. Gamet
acting District Director
New Orleans District

/tjt

Enclosure: FDA-483